MonaLisa Touch

MonaLisa Touch Fractional Co2 Laser

Scientific Update 2022

Monalisa Touch was established in Australia in 2013, as a fractional CO2 laser treatment that treats symptoms of vaginal atrophy (Genitourinary Syndrome of Menopause) .

Your specialist will assess your own circumstances to determine your clinical signs and symptoms to determine the most appropriate management plan.

This document is not designed to replace a clinical consultation but rather to summarize the Scientific Research available as of 2022. The Monalisa treatment is available worldwide, and, as expected has resulted in a large amount of published data in Scientific journals.

The results and outcomes continue to be positive for patients. In 2022, a published analysis of 52 000 patients who have had the treatment (combining published data from over 100 published studies) reported women experienced a significant improvement after exposure to vulval or vaginal laser across all indications, with no serious adverse events. *(Acta Obstet Gynecol Scand 2022:00: 1-36).*

PUBLICATIONS IN SCIENTIFIC JOURNALS UP TO 2022 CONTINUE TO PROVIDE EVIDENCE OF POSITIVE OUTCOMES.

Importantly, the studies include Cochrane reviews (a British organisation the organises medical research findings to facilitate evidence-based choices about health interventions), an number of randomized trials comparing the treatment with topical oestrogen therapy and sham treatments, and most of the studies are prospective (a better quality of study than retrospective).

PATHOLOGY STUDIES - Tissue changes in histology or pH

Zerbinati et al.*Lasers Med Sci. 2015 30:429-436*	Observational n=5	Fibroblast improvement, r- ER. Improved epithelial thickness. Large amount of glycogen. Improved blood flow	No serious adverse effects
Salvatore et al. *Menopause 2015;22. 845-9*	Cohort Study n=5 Postmenopausal	Changes in epithelium and lamina propria. Fibroblasts activated. Positive effects on collagen and elastin.	No adverse effects
Athanasiou et al. *Climacteric. 2016: 19:512-518*	Cohort Study n=53	Increased lactobacillus to improve vaginal pH and vaginal epithelium	No adverse effects
Salvatore et al. *Maced J Med Sci. 2018: 6: 6-14*	Case report	Thicker epithelium. Connective tissue improved fibroblasts and blood vessels.	No adverse effects.
Becorpi et al *Lasers Med Sci 2018:33:1047-1054*	Cohort Study n=20 Postmenopausal	High remodelling status in vaginal epithelium. Changes in cytokines	No adverse effects
Pagnano et al *Lasers Surg Med 2021:53:521 - 518*	Cohort Study n=20	Improved vulvar epithelium, remodelling of connective tissue, new blood vessels	No adverse effects

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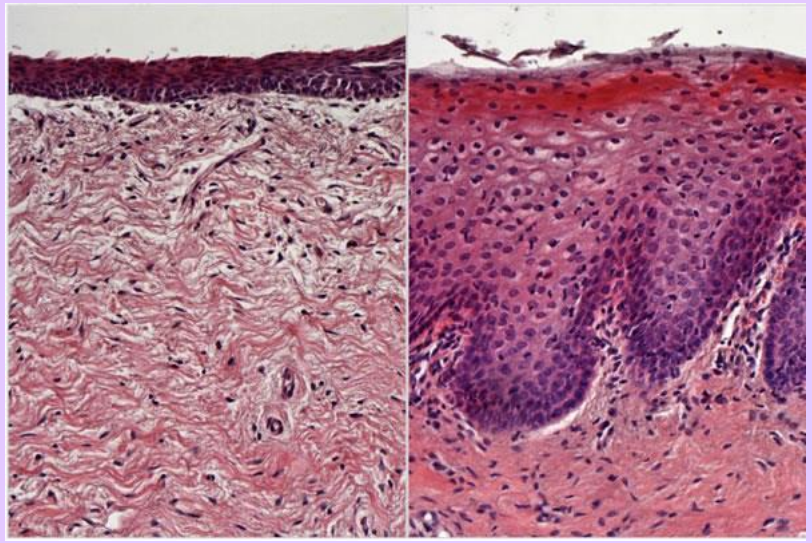
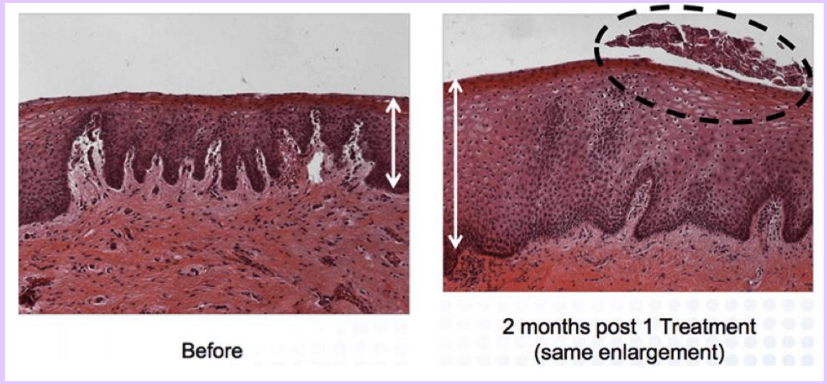
PATHOLOGY STUDIES - Tissue changes- before and after vaginal fractional laser





The photomicrographs on the left (pre treatment) show thin, atrophic vaginal mucosa.

The right (post treatment) demonstrate images at the same magnification. The surface now has thicker epithelium, more glycogen (moisture) in the cells with more active tissue and cell turnover.

Randomised Controlled Trials – Atrophy, Genitourinary Syndrome Menopause

Cruz et al .*Menopause. 2018 25:21-28* (Brazil)	Comparison of estriol(E) v laser(L) v laser with estriol(L+E)	N=45 . Outcome at 20 weeks	Improvements in all groups. L+E -improved Vaginal Health Index and Female Sexual Function. L+E and L- improved burning and dryness
Politano et al. *Menopause. 2019.26 - 833-840.(Brazil)*	Comparison Co2 Laser(L) v estrogen cream(E) v lubricant(Gel)	N=72. Outcome at 14 weeks	Significant improvement of vaginal health. Laser higher than estrogen higher than gel.
Ruanphoo *Menopause. 2020:27: 858-863 (Thailand)*	Laser v Sham laser	N=88. Outcome at 12 weeks.	Significant improvement in laser v sham with VHI (Vaginal Health Index) VAS (visual analog score and less pain
Paradiso et al 'Velvet trial' *Menopause. 2020;27:50-56 (USA)*	Laser v Vaginal Estrogen	N=69 Outcome at 6 months	Improved Visual Analog Scores from baseline to follow up. Both groups improved. No difference L vs E.
Salvatore et al. *Climacteric:2020:24:187-193 (Italy)*	Laser V Sham Laser	N=58. Outcome 1 month after 3rd laser	Significantly lower dryness and dyspareunia (painful intercourse) in Laser v Sham Laser group
Dutra et al .*Menopause : 2021 :28: 756-763 (Brazil)*	Laser v Vaginal Estrogen	N=25. Outcome 1 month after 3rd laser	Significant improvement in vaginal thickness in both groups (laser and estrogen)
Li et al . *JAMA. 2021:326:1381-1389 (Australia)*	Laser v Sham Laser	N=85. Outcome at 12 months	Overall no significant difference in VAS, but scores improved in both groups at follow-up
Cruff et al(*J Sex Med:2021: 18:761-769 (USA)*	Laser v Sham Laser	N=34. Outcome at 6 months	This study lacked power to determine a difference between each treatment arm
Quick et al. Maturitas. 2021:144: 37-44	Laser v Sham Laser	N=18. Outcome 1 month afer 3rd laser	No significant difference in VAS (visual analog score) between the groups.

Cohort Trials – 2021 / 2022 -CO2 laser treatment for atrophy

Alexiades. *Lasers Surg Med 2021:53 (USA).* N= 18. Significant improvement VHI (vaginal health index) and FSFI (female sexual function index) at 12 months
Bretas et al *Climacteric 2022 :25* (*Brazil)* N=14. Significant improvement in VHI and FSFI
Gardner & Aschkenazi *Menopause 2021:28 (USA)* N=139. Significant improvement in FSFI , improved scores for intercourse and less dryness
Li et al *Lasers Surg Med 2021:53 (China)* N= 162. Both laser and vaginal oestrogen cream (compared) improved vaginal health at 12 months in both the laser and the vaginal oestrogen treated groups
Luvero et al *Lasers Med Sci 2021;36 (Italy)* N=44. The laser group (compared to the no treatment group) had significant improvement in all symptoms
Quick et al *Menopause 2021:*28 *(USA)* N=67. Significant improvement in FSFI. At 12 months some problems with Sexual intercourse still present.
Roser-Tenerowicz et al *Ginekol Pol 2021 (Poland)* N=205. Significant improvement in VHIS and VAS(Visual analog scores)
Ruffolo et al *Lasers Surg Med 2021 :53 (Italy)* N=61. Significant improvement in vulvovaginal atrophy symptoms.
Salvatore et al *Clin Breast Cancer 2021:21 (Italy)* N=40. Effects of laser comparing past users of hormone treatment. Study found both patients who had or had not previously used estrogen had a significant improvement in VAS and VHI . Both groups had the same benefit.
Silinqui et al *Breast J 2021:27 (Italy).* N=135 . Laser improved dryness and dyspareunia in patients both with and without a history of breast **cancer**.
Sindou-Faurie et al *Arch Gynecol Obstet 2021:303. (France)* N=46. Significant improvement in dryness and stress urinary incontinence
Veron et al *Breast Cancer Res Treat 2021:188 (France)* N = 46 Improved cell maturity and vaginal pH. Improved FSFI

Cohort Trials – 2020 CO2 laser treatment for atrophy

Adabi et al *J Lasers Med Sci 2020:11.(Iran)* N=140. Significant improvement arousal, vaginal elasticity, fluid, satisfaction

Angioli et al *Int J Gynecol Cancer: 2020; 30(Italy)* N=165.Improved vulvovaginal atrophy symptoms on visual analog scale

Di Donato et al *Matuitas 2020 (Italy)* N=53. High satisfaction in 89%

Filippini et al *Menopause 2020:27 (Italy)* N=645. Significant improvement in dryness, dyspareunia, burning, pain, itching

Ghanbari et al *J Fam Reprod Health 2020:14 (Iran)* N=47 Significant improvement in Visual Analog Scale for Vulvovaginal atrophy symptoms.

Hersant et al *Ann Chir Plast Esthet 2020: 65 (France)* N=20. Significant improvement vaginal elasticity, fluid volume, epithelial integrity and moisture

Marin et al *J Gynecol Otstet Hum Reprod 2020:49.(France)* N=50 Significant improvement FSFI (female sexual function index) and quality of life

Mezzana et al *Dermatol Thera 2020:33 (Italy)* N= 40. Significant improvement in FSFI and stress urinary incontinence

Takecs eet al *Lasers Surg Med 2020:52 (USA)* N=*52* Significant improvement in visual analog scores and vaginal maturation

Cohort Trials – 2018 & 2019 CO2 laser treatment for atrophy

Athansiou et al *Menopause 2019:26 (Greece).*N=94 Significant improvement in VAS(visual analog scale) and FSFI(female sexual function index) after 3, 4 or 5 treatment sessions. 5 sessions had similar results to 4 sessions.

Eder et al *Laser Ther2018:28 (USA)* N=*28.* Significant improvement in VHI (Vaginal Health Index) from baseline to 6 months

Eder et al *Laser Ther 2019:28 (USA)* N=20. Significant improvement in VHI (Vaginal Health Index) at 12 15 and 18 months

Gittens et al *J Cosmet Laser 2019:21(USA)* .N=25 . Significant improvement in every domain of FSFI

Murina et al *Gynecol Endocrinol 2019:36 (Italy)* N=*72.* Significant improvement in dryness with laser patients as well as laser +ospemifene patients (laser +ospemifene– not available in Australia – better than laser alone

Pearson et al *Breast Cancer Res Treat: 2019;178 (Australia)* N=29 Significant improvement in dryness, burning and dyspareunia

Quick et al *Support Care Cancer :2019 :28.(Germany)* N=64. Improvement in VAS FSFI and Urinary Diary

Samuels et al *Aesthet Surg J:2019:39 (USA)* N=40 Signficant improvement in VHI at 6 months, and in all evaulations

Singh et al *J Gynecol Surg 2019:35* N=45. 90% of patients improved dryness, 89.5% improved dyspareunia

Tovar-Huamani et al *Lasers Surg Med 2019:51.* N=60. Improvement in VAS for genitourinary syndrome of menopause

Cohort Trials – 2017 CO2 laser treatment for atrophy

Athansiou et al *Maturitas 2017:104 (Greece)* N=55 Significant improvement after 3rd session

Arroyo et al *Int J Womens Health2017:9* (*Spain)* N=21 Significant improvement in VHI (vaginal health index) 12 weeks and 24 weeks after last treatment

Behnia-Willison *Eur J Obstet Gynecol Reprod Biol 2017 :213 (Australia)* N=102 Significant improvement in GSM (Genitourinary syndrome of Menopause) symptoms at 2, 4, 12 and 24 months

Filippini Et al *Photomed Laser Surg2017:35 (Italy)* N=386 2 months after last treatment patient reported improvement

Lang et al *Lasers Surg Med 2017:49 (USA)* N=368 Significant improvement in dryness ; reported satisfaction 86%

Pitsdouni et al *Lasers Med Sci2017:32 (case control study)* within group improvement significant

Pagano et al *Menopause :2017:25(Italy)* N=82 Significant reduction vulvovaginal symptoms. No improvement in laxity.

Pieralli et al *Arch Gynecol Obstete 2017:296 (Italy)* N=184 92% satisfaction at 6 months, 25% satisfaction at 24 months

Siliquini et al *Climacteric 2017: 20 ((Italy)* N=91 Significant improvement in VHI VAS at 15 month follow up

Sokol et al *Menopause 2017:24 (USA)* N=30. Significant improvement in VAS in first year (except dysuria)

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Cohort Trials – 2014 to 2016 CO2 laser treatment for atrophy

Letskulchi et al *J Med Assoc Thai 2016 : 99 (Thailand)* N=112 . Significant improvement pHand pH

Murina et al *J Sex Med 2016:13 (Italy)* N=70 Significant improvement atrophy including at 4 month follow up

Pagano et al *Menopause 2016: 23 (Italy) N=26* Breast cancer survivors – significant improvement in VAS (except laxity)

Perino et al *Maturitas 2014:80 (Italy)* N=48 Significant improvement in VAS scores andVHI

Pierelli et al *Arch Gynecol Obstet 2016: 294 (Italy)* N=50 Breast cancer survivors – significant improvement VH*I and* VAS

Pitsouni et al *Maturitas 2016 :94 ((Greece)* N=53 Significant improvement atrophy

Sokol et al *Menopause 2016:23 (USA)* N=30 Significant improvement in VAS for all categories

Salvatore et al *Climacterc 2014:17 (USA)* N=50 Significant improvement in VVA stores except for burning

Salvatore et al *Cimacteric 2014:*18 (USA) N=77 Significant improvement in FSFI

Treatment to External Labia and Vaginal Canal With CO2 Laser for Symptoms of Vulvovaginal Atrophy in Postmenopausal Women. Julene B Samuels, Martin A Garcia

Aesthet Surg J 2019 Jan 1;39(1):83-93.doi: 10.1093/asj/sjy087

Forty postmenopausal women were treated extravaginally and internally with a fractional CO2 laser. Objective measurements of vaginal health index, as well as subjective measurements of symptoms of vulvovaginal atrophy (VVA), urinary incontinence, and sexual function were reported at baseline. Follow-up evaluations were at one, three, six, and 12 months after the third treatment.
Vaginal health index improved significantly after the first treatment and was maintained with mean improvement of 9.6 ± 3.3 ($P < 0.001$) and 9.5 ± 3.3 ($P < 0.001$) at the 6- and 12-month follow ups, respectively. Vaginal symptoms of dryness, itching, and dyspareunia improved significantly ($P < 0.05$) at all evaluations. Histological findings showed increased collagen and elastin staining, as well as a thicker epithelium with an increased number of cell layers and a better degree of surface maturation.
They concluded 'Fractional CO2 laser treatments were well tolerated and were associated with improvement in vaginal health and amelioration of symptoms of VVA. Histological changes in the epithelium and lamina propria, caused by fractional CO2 laser treatments, correlated with clinical restoration of vaginal hydration and pH to premenopausal levels.'
Because the authors presented pathology biopsies (objective outcomes) that correlated with clinical improvement (subjective outcomes) this study is of scientific value.

Efficacy of fractional CO2 laser treatment in postmenopausal women with genitourinary syndrome: a multicenter . Maurizio Filippini et al.

Menopause. 2020 Jan;27(1):43-49. doi: 10.1097/GME.0000000000001428.

Fractional CO2 laser system (SmartXide VLR, Deka m.e.l.a., Florence, Italy) in Six hundred forty-five women who met the inclusion criteria were considered. The pre- and post-treatment averages of the symptoms, the standard deviation, and the P values were calculated.In all the parameters examined (dyspareunia, vaginal orifice pain, dryness/atrophy, itching, burning, pH) statistically significant data were found between the pretreatment and the post-treatment (dryness: before = 8.30, after = 2.97 [P < 0.0001], dyspareunia: before = 8.70, after = 3.51 [P < 0.0001]; burning: before = 6.12, after = 1.78 [P < 0.0001]; vaginal orifice pain: before = 8.07, after = 2.94 [P < 0.0001]; itching: before = 6.09, after = 1.32 [P < 0.0001]).

They concluded ‘effectiveness and a good degree of tolerance of treatment’.

This study has the benefit of a large number of women, however it was a retrospective observational study which has some scientific limitations compared with any prospective study.

Effect of the Fractional CO_2 Laser on the Quality of Life, General Health, and Genitourinary Symptoms in Postmenopausal Women With Vaginal Atrophy: A Prospective Cohort. Khadijeh Adabi et al.

J Lasers Med Sci. Winter 2020;11(1):65-69.

doi: 10.15171/jlms.2020.11. Epub 2020 Jan 18.

This prospective study was conducted among 140 women from 2017 to 2018, having in CO2 laser system three times at four-week intervals. The short form of the Health Questionnaire (SF-12) and the Female Sexual Functional Index (FSFI) questionnaire, the vaginal health index (VHI) and International Consultation on Incontinence Questionnaire (ICIQ) Form were used to evaluate the quality of life. It improved significantly in somatic, social function, and mental health. In the sexual context, arousal and satisfaction status improved significantly. Also, the frequency of urinary incontinence, enuresis, urgency, and the leak improved significantly ($P<0.05$). Among the scale variables for urinary function, it was seen that the urgency impact had no improvement. All vaginal indices improved ($P<0.05$).

They concluded 'fractional CO_2 laser can be effective in treating vaginal atrophy and urinary symptoms'.

The study is observational and prospective; however a control arm would have been a useful addition to exclude any other confounding variables, *inter alia* a placebo effect or other scientific bias that is possible.

AUGS Clinical Consensus Statement. Ashliek et al

Female Pelvic Medicine & Reconstructive Surgery. Vol 26, Number 5, May 2020.

https://www.augs.org/assets/1/6/Vaginal_Energy_Based_Devices.3.pdf

This well researched article from the American Urogynaecology Society looks at ***all*** energy based vaginal devices (EBD), and acknowledge the significant differences between non-ablative devices, fractional CO2 laser (eg Monalisa Touch smartxide DEKA) , hybrid lasers, and the different category of radiofrequency devices. In total 28 statements reached consensus by the working parties; the 12 statements that did not reach consensus were a result of an absence of evidence.

Listed are some of the consensus statements.

EFFICACY: A statement that reached consensus is that 'EBD therapy has shown promise in treatment of VVA, vaginal dryness, and menopausal **dyspareunia'. The statement concluded that 'overall most published articles are small, short case series that measure a variety of outcomes'.**

TIMING: 'The AUGS EBD writing group reached consensus that the benefits of fractionated laser therapy to treat menopausal dyspareunia may last up to 1 year', and 'vaginal CO2 laser therapy has been shown to be effective in treatment of VVA in several studies up to 20 weeks'.

COST-EFFICACY DATA: 'There are no comparative cost-efficiency data for EBD therapy versus available medical and surgical therapies for GSM/VVA'.

OTHER THERAPIES: 'Pretreatment criteria for EBD therapy may include inability to use vaginal estrogen treatment for menopausal dyspareunia, VVA or vaginal dryness…But there are insufficient data to demonstrate the safety of vaginal oestrogen for women with breast cancer'.

SAFETY: All 6 drafted statements on the safety of vulvovaginal EBD therapy achieved consensus….the AUGS EBD writing group largely agreed that.. (these) therapies have a favorable safety profile', but 'the long-term sequelae of vulvovaginal EBD therapy are unknown'.

WHAT IS THE RISK OF HORMONE TREATMENTS WITH A HISTORY OF BREAST CANCER ? WHAT IS THE ALTERNATIVE TO LASER ?

NAMS Position Statement. The 2020 genitourinary syndrome of menopause position statement of the North American Menopause Society. *Menopause 27 (9). pp976-992*

https://www.menopause.org/docs/default-source/default-document-library/2020-gsm-ps.pdf

This document contains some helpful data on treatment options **other than laser**, and stresses that 'there is insufficient data at present to confirm the safety of vaginal estrogen or DHEA in women with breast cancer'; recommends 'non-hormonal therapies for women with mild symptoms'; and calls for 'more placebo-controlled trials..of laser(therapies)'.

Treatment for vaginal atrophy using microablative fractional CO2 laser: a randomized double-blinded sham-controlled trial

Ruanphoo , Bunyavejchevin

Menopause. 2020 Aug;27(8):858-863. doi: 10.1097/GME.0000000000001542.

A total of 88 postmenopausal women with moderate to severe intensity of any vaginal atrophy symptoms (VAS) were invited to participate in the study. women were randomized to receive treatment with either vaginal CO2 laser or sham procedures every 4 weeks for three sessions. Both the participants and the evaluators were blinded to the treatment. Vaginal Health Index (VHI) score (primary outcome), VAS score, and the item for vaginal dryness from the International Consultation on Incontinence Modular Questionnaire-Vaginal Symptoms questionnaire were compared between the two groups by intention-to-treat analysis at 12 weeks after treatment. Of the 88 women, 9 women were lost to follow-up. After 12 weeks of laser treatment, the VHI, VAS, and International Consultation on Incontinence Modular Questionnaire-Vaginal Symptoms (item for vaginal dryness) scores were significantly improved. For VHI and VAS scores the mean difference between the laser group versus the sham group was 1.37 (95% CI: 0.12-2.63), $P < 0.001$ and -1.52 (95% CI: -2.21 to -0.82), $P = 0.03$, respectively.

They concluded 'microablative fractional CO2 laser was effective in treating vaginal atrophy. It could be a promising alternative treatment for postmenopausal women with vaginal atrophy'.

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Effects of local laser treatment on vulvovaginal atrophy among women with breast cancer: a prospective study with long-term follow-up. Veron et al.

Breast Cancer Res Treat. 2021 Jul;188(2):501-509. doi: 10.1007/s10549-021-06226-3. Epub 2021 Apr 23.

Women with breast cancer (BC) often suffer from severe vulvovaginal atrophy (VVA). This prospective study among women with BC and VVA, evaluated the effect of fractional microablative CO_2 laser therapy once per month for 3 months. Efficacy of laser therapy was assessed at baseline, 6 months and 18 months after treatment, using Female Sexual Function Index (FSFI) score, and vaginal pH. A pap smear was also performed and the epithelial maturation pattern was noted. Paired statistical tests were used to compare results between baseline, 6 months and 18 months. Of the 46 women with BC (median age 56.5) years, the PH level slightly decreased over time (mean Δ at 18 months -0.3, SD = 0.7, p = 0.02) whereas maturation pattern on pap smear did not change. Sexual quality of life was significantly improved at 6 months and 18 months (mean Δ at 6 months 8.3, SD = 6.2 ($p < 0.0001$) and mean Δ at 18 months 4.3, SD = 8.4 (p = 0.01)).

They concluded 'women with BC, fractional microablative CO_2 laser is effective on the long term on VVA symptoms and gynaecological quality of life.'

Conflict of interest statement by the authors. The microablative laser was provided by DEKA. There was no financial support from DEKA.

Efficacy of CO_2 laser treatment in postmenopausal women with vulvovaginal atrophy: a meta-analysis. Liu et al.

Int J Gynaecol Obstet. 2021 Oct 8.doi: 10.1002/ijgo.13973.

PubMed, Embase, Cochrane Library and Web of Science were searched to June 9th, 2020. Prospective studies on the efficacy of CO_2 laser treatment were included. Twelve literatures including 459 participants were enrolled. Compared to baseline, VHIs were significantly higher at 1-, 3-, 6-, and 12-month follow-ups ($P<0.001$). For VVA severity, VAS scores in vaginal dryness at 1-, 3-, 6-, and 12-month follow-ups ($P<0.050$), in vaginal burning, itching and dysuria at 1-month follow-up ($P<0.001$), and in dyspareunia at 1-, 3-, 6-, and 12-month follow-ups ($P<0.001$) were all significantly lower. For FSFI, total scores at 1-, 3-, 6-, and 12-month follow-ups ($P<0.001$), and the scores in desire, arousal, lubrication, orgasm, satisfaction, and pain at 1-month follow-up ($P<0.050$) were all significantly higher. For QoL, PCS12 and MCS12 scores were all significantly higher ($P<0.050$) at 1-month follow-up.

They concluded "CO_2 laser treatment may be effective for post-menopausal women with VVA symptoms in improving QoL and sexual function."

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Climacteric Volume 23, 2020 - Issue sup1: Vaginal lasers in gynecology: the peer-reviewed Proceedings of the 5th VELA Meeting

Hillard Tim Hillard, Consultant Gynaecologist University Hospitals Dorset, Poole, UK**Published online: 30 Oct 2020**

- https://doi.org/10.1080/13697137.2020.1774536

Hillard's publication reviews indications for transvaginal laser therapies, particularly genitourinary syndrome of the menopause and stress urinary incontinence. The article reviews the current data pertaining to the place of these devices in current clinical practice.

"The evidence suggests that vaginal laser therapy with either the erbium-doped yttrium aluminum garnet laser (FotonaSmooth®) or the CO_2 laser (MonaLisa Touch®) is an effective intervention for the relief of symptoms of vulvovaginal atrophy in symptomatic women. The benefits of three laser treatments appear to last for at least 12 months and the procedure is generally well tolerated, with transient minor discomfort being the most common adverse event. Whilst there has been a rapid increase in the number of publications over the last few years, many of the studies are of small numbers, short duration, and poor quality and are device-sponsored."

He states that "the vaginal laser certainly has the potential to be an alternative treatment to vaginal estrogens for those groups of women, such as breast cancer patients, who cannot take them, there are still many unanswered questions".

Some of the questions pertain to some less clear indications for this treatment (for example, see the following review on lasers for symptomatic genital prolapse), and Hillard encourages further research.

The author of this website, Dr Burrows, agrees that more research and data examining these so called 'minor', (but in reality often distressing symptoms for many women) is to be welcomed.

Pelvic Organ Prolapse and Lasers (1)

When you make your initial consultation you will be assessed by a gynaecologist. Most patients who suffer the symptoms of pelvic organ prolapse are initially referred to a qualified pelvic floor physiotherapist, and offered topical oestrogen treatment (if suitable). In addition, significant prolapse that requires surgical repair may be referred to a subspecialist called a Urogynaecologist, who performs and advises of the risks and benefits of surgical correction.

The following well designed study from the urogynaecology department in Athens is a randomized, assessor-blinded controlled trial of the Erbium YAG smooth laser in postmenopausal women with symptomatic stage 2 or 3 vaginal prolapse who had opted to undergo surgery. Please note that this is NOT the Monalisa Touch, although the science is relevant to both devices.

Athanasiou S, Pitrrantouni E, Cardozo L et al. Can pelvic organ prolapse in postmenopausal women be treated with laser therapy? Climacteric 2020. https://pubmed.ncbi.nlm.nih.gov/32720552/

The study found that after three Er:YAG laser treatments, there was no improvement in the pelvic anatomy as judged by the POP-Q assessment, and none of the participants in this study were objectively or subjectively cured following laser therapies. There were no changes in the patient-reported outcomes, and the laser therapy results were no different from those of the watchful-waiting group.

Pelvic Organ Prolapse and Lasers (2)

No adverse events were reported by any of the participants.

The authors conclude that their study results do not support the use of intravaginal Er:YAG laser as a therapeutic option in postmenopausal patients with symptomatic pelvic organ prolapse, defined in the study as '***the problem as pelvic floor prolapse for women who felt that there symtoms were so significant that they would undergo surgical correction'*.**

IMS Live (International Menopause Society) comments on the Australasian Menopause Society publication, December 2020:

"***Whether or not the laser could have a potential role in women with mild asymptomatic POP and perhaps prevent progression or deterioration of its severity is speculative and would need further analysis in appropriately conducted trials. Any such trials should include assessing laser therapy alongside and in combination with other standard conservative therapies (i.e. pelvic floor muscle training)".***

After topical oestrogen therapies, pessaries and pelvic floor training from a physiotherapist, some women feel that they need to consider surgical intervention. The trial participants were at that stage. Surgery for POP (pelvic organ prolapse) does, of course, have its risks (Baessler K, Christmann-Schmid C, Maher C et al. Surgery for women with pelvic organ prolapse with or without stress urinary incontinence. Cochrane Database Syst Rev 2018;8:CD013108. https://pubmed.ncbi.nlm.nih.gov/30121956/) so anything along the clinical pathway that may prevent deterioration is worthy of further study.

Is there enough evidence to justify the use of laser and other thermal therapies in female lower urinary tract dysfunction? Report from the ICI-RS 2019

Robinson D et al, Neurourol Urodyn. 2020 Jul;39 Suppl 3:S140-S147.

https://pubmed.ncbi.nlm.nih.gov/32040871/

The evidence for SUI (Stress Urinary Incontinence) is reviewed in the latest edition of Climacteric.

They concluded that **“**The current available evidence, though of low or very low quality, appears promising for the use of laser therapy in the management of genitourinary syndrome of the menopause, there are some data to suggest a possible role in SUI although very little evidence for urogenital prolapse.”

The last statement is in concordance with the Pelvic Organ Prolase study above (Athanasiou), but does lend support to the current use of lasers for urinary stress incontinence. Again, I would stress that in our practice we take a careful assessment (for example urgency and stress incontinence can exist separately or as a mixed picture). Often exclusion of other pathology such as prolapse or urine and vaginal infections is necessary.

We will always adopt a wholistic approach which will often involve others such as qualified pelvic floor physios, expert in management of bladder disorders and training, as well as all options for prolapse management (both surgical and non-surgical), along with management of secondary issues resulting from disease (vaginismus,pain,psychosexual issues).

Effectiveness of CO_2 laser on urogenital syndrome in women with a previous gynecological neoplasia: a multicentric study.

Angioli, R. et al .

Int J Gynecol Cancer. 2020 Mar 27. pii: ijgc-2019-001028. doi: 10.1136/ijgc-2019-001028. [Epub ahead of print]

https://www.ncbi.nlm.nih.gov/pubmed/?term=effectiveness+of+co2+laser+on+urogenital+syndrome+in+women+with+a+previous+gynecological+neoplasia

This retrospective study was conducted in four European centres between November 2012 and February 2018. Patients included had a history of breast, ovarian, cervical, or uterus cancer, suffer vulvovaginal atrophy and at least one symptom of urogenital syndrome: vaginal dryness, dyspareunia, vaginal introitus pain, burning or itching. Patients underwent the standard three treatments and symptoms were evaluated before and after the treatments using a VAS (Visual Analog Scale). Dryness improved by 66%; dyspareunia improved by 59%; burning improved by 66%, pain at the introitus improved by 54% and itching improved by 54%. No side effects were seen in any sessions. The authors concluded “Fractional microablative CO2 laser therapy offers an effective strategy in the management of the symptoms of genitourinary syndrome in postmenopausal women and in survivors of gynecological cancer”.

CLEVELAND CLINIC OHIO VeLVET trial (1)

A study has been published by The Cleveland Clinic Ohio, USA which demonstrated the benefit of laser therapy compared with vaginal oestrogen. The Ohio Clinic is ranked No. 4 in the USA Best Hospitals Honor Roll, and the study was published in *Menopause*, the journal of the North American Menopause Society (NAMS).

The study compares effectiveness and safety of fractionated CO2 vaginal laser therapy with vaginal estrogen after 6 months of follow-up with postmenopausal women CLEVELAND, Ohio (October 2, 2019)—

Nearly 50% of menopausal women complain of vaginal dryness, itching, and burning, among other commonly reported menopause symptoms. Laser therapy is one of the newer techniques for addressing these problems. A new study suggests that it is as effective and safe as vaginal estrogen in improving sexual and urinary functionality. Results are published online today in Menopause, the journal of The North American Menopause Society (NAMS).

As a result of declining estrogen levels during menopause, women may experience a variety of genital and urinary problems such as vaginal dryness, reduced elasticity, vaginal burning, discharge, and itching, collectively known as the genitourinary syndrome of menopause (GSM). Such symptoms are the result of the vagina decreasing in caliber and the constriction of the vaginal opening.

The first line of defense in addressing these symptoms, assuming they are mild, is often prescribing vaginal lubricants or moisturizers. Women with more severe symptoms may be prescribed vaginal estrogen, which has proven highly effective and safe. A drawback of vaginal estrogen therapy, however, is that women don’t always follow through with it. Studies have shown that compliance rates vary from only 50% to 74%. In addition, there is a lack of long-term efficacy data, especially in high-risk women, such as those with breast or uterine cancer.

CLEVELAND CLINIC OHIO VeLVET trial (2)

More recently, fractional CO2 laser therapy has been suggested as a viable treatment option. Lasers have already been effectively used on other parts of the body to remodel tissue and produce new collagen and elastic fibers. Their use for treatment of vaginal symptoms related to menopause is still somewhat new, with most studies reporting results just 12 weeks after the procedure. This latest study is the first to compare the safety and effectiveness of laser therapy with vaginal estrogen after 6 months of follow-up.

At 6 months, researchers found that laser therapy and vaginal estrogen resulted in similar improvements in GSM symptoms, as well as urinary and sexual function. They reported that 70% to 80% of study participants were satisfied or very satisfied with ether treatment option, with no serious adverse effects.

Findings were published in the article “A randomized clinical trial comparing vaginal laser therapy to vaginal estrogen therapy in women with genitourinary syndrome of menopause: The VeLVET Trial.”

For a link to the article please click

https://www.ncbi.nlm.nih.gov/pubmed/31794500/